HERBALIFE.

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. 2004N-0230: Current Good Manufacturing Practice Regulations

To Whom It May Concern:

Herbalife International, Inc. ("Herbalife") is submitting these comments to the Food and Drug Administration ("FDA") in response to the May 21, 2004 Notice "Food; Current Good Manufacturing Practice Regulations; Public Meetings," 69 Fed. Reg. 29220 (May 21, 2004).

As a science-based innovator, Herbalife develops and markets conventional foods, dietary supplements and cosmetics that promote healthy living. The company was founded more than 24 years ago in California, reported $1.2 billion in net sales for 2003 and offers more than 150 different products to consumers around the world. Herbalife's products are marketed through a global network of more than 1,000,000 independent distributors in 59 countries.

Herbalife distributes a large number of food products under the ShapeWorks™, HPLC and Herbalife trade names. Our conventional foods and dietary supplement products sold in the United States currently are being produced by a number of contract manufacturers operating within the United States and Canada.

It has long been part of Herbalife's standard operating procedure to monitor the quality standards employed by these contractors to verify that they meet or exceed the current Good Manufacturing Practice (GMP) requirements outlined in 21 C.F.R. Part 110. It is our view that FDA's GMPs have played a key role in ensuring the quality of food products.

In order to guarantee the continued high quality of its products, Herbalife supports any effort by FDA to strengthen or otherwise improve the impact of GMPs on the manufacturing of food. Herbalife applauds FDA for taking the time to elicit comments from industry and other interested parties on GMPs and urges FDA to respond to these comments by modernizing the GMP regulations.

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Specifically, Herbalife urges FDA to refine the food GMPs so that: (1) allergens are accurately identified, tracked, recorded, and disclosed on the label; and (2) all added ingredients are accurately measured, permitting labeling to be more precise.

Allergens

Herbalife's products are purchased by a broad range of consumers interested in maintaining their health. For these consumers – and the public in general – the presence or absence of allergens can be a life or death matter. Companies, such as Herbalife, are eager to ensure the safety of these consumers, and do so by disclosing on product labels the presence of known allergens.

GMPs, in addressing product content, should take our interest in disclosing allergens into account. As currently written, however, the food GMPs do not mandate that the presence of potential allergens in food products be identified, tracked, or disclosed. In this sense, the GMPs do not serve the needs of consumers and companies.

For this reason, Herbalife supports the adoption of these specific measures within the food GMPs that would require the identification, tracking, cleaning and label disclosure of potential allergens used in manufacturing facilities:

- Identification of Allergens: FDA should develop a list of ingredients that are potentially allergenic.
- Tracking of Allergens: The revised GMPs should then require manufacturing facilities to tracking the use of any of these allergenic ingredients on or in each piece of equipment.
- Communication to Producers: Revised GMPs should mandate the communication of this tracking list to all food producers and distributors who produce food at that manufacturing facility.
- Disclosure of Allergens: GMPs should further require the disclosure of all identified allergens on the labels of all food products produced on the identified equipment.
- Exception: An exception to this rule could be developed if a manufacturer undertakes an appropriate cleaning process to remove traces of allergens from the equipment. If a manufacturing facility documented the use of such a cleaning process, it would communicate this information to the food producers who would then not have an obligation to disclose potential allergens on the label.

A process based on this model would ensure that allergens were accurately identified, tracked, and disclosed on product labels. It would thus protect the public from adverse reactions.

Moreover, adoption of such requirements would be commensurate with recently identified national priorities. The "Food Allergen Labeling and Consumer Protection Act" (S.741), approved by Congress July 20, 2004, already directs FDA to identify allergens on food labels and, *inter alia*, to consider whether a change in the food GMPs

can address the issue of identifying potential allergens. Clearly, measures such as those proposed above could satisfy this expressed Congressional interest.

Accuracy of Ingredient Measurements

Like other manufacturers and distributors, Herbalife has faced situations in which imprecision in manufacturing processes has created overages or underages in the quantities of food ingredients added to a product. Inaccurate ingredient measurements may ultimately lead to inaccurate fill weights and net weight declarations on product labels. Herbalife urges FDA to revise the food GMPs to help ensure more accurate ingredient measurements.[1]

To the extent that these inaccuracies result in products whose declared ingredients (*e.g.*, calories, calories from fat, or other nutrients) vary from what is actually present, there is a clear misbranding issue. Misbranded products could lead to consumer deception and potential ill will in the marketplace.

To correct this problem, Herbalife has long required contract manufacturers to guarantee the identity and specifications of ingredients. Herbalife regularly audits manufacturing facilities to ensure that ingredients quantities conform to the company's specifications. However, Herbalife cannot be present during the manufacturing process of every one of its products; thus, inaccuracies occasionally result.

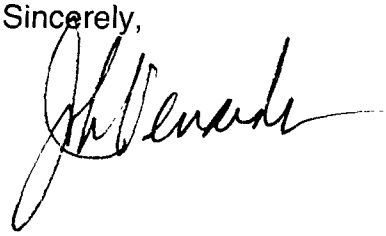
In order to reduce the potential for misbranding and consumer deception, FDA should revise the GMPs so that every ingredient measurement in a manufacturing process must be verified and recorded for every manufacturing step. The additional burden to manufacturing facilities would be slight – only necessitating an additional recordkeeping step – while the benefit to consumers would be significant. The net gain would be more accurate labeling, allowing consumers to shape and plan their eating regimes.

Conclusion

Herbalife appreciates FDA's ongoing efforts to ensure compliance with food GMPs by regular inspections of manufacturing facilities.

Herbalife believes that updating the food GMPs so that: (1) allergens are accurately identified, tracked, recorded, and disclosed on the label; and (2) ingredients are accurately measured will improve the safety of the food supply.

Sincerely,



[1] Herbalife recognizes that enforcement of net weight accuracy issues are generally under the jurisdiction of state departments of weights and measures. However, the company believes that FDA also has a significant, persuasive role to play as well.